

REMARKS

This responds to the Office Action dated September 17, 2003.

Claims 2, 4, 9, 13, 15 – 18, and 29 – 30 are amended. No claims are canceled or added. As a result, claims 2 – 35 are now pending in this application.

For brevity, Applicant does not repeat remarks in support of patentability that have already been made of record. Instead, Applicant focuses the present remarks on the Examiner's helpful clarifications newly provided in the September 17, 2003 Final Office Action.

Telephone Interview Summary

On September 28, 2003, a call was placed to Examiner Oropeza seeking clarification on the status of the application. The cover sheet of the office action mailed September 17, 2003 indicated the action was final, but the conclusion of the action did not. Examiner Oropeza reviewed the application and confirmed, by way of voice mail, that the office action was final.

§102 Rejection of the Claims

1. Claims 1 – 12 and 15 – 35 were rejected under 35 U.S.C. § 102(b) for anticipation by Combs et al. (U.S. Patent No. 5,957,861). Applicant respectfully traverses.

As discussed in Applicant's previous response, Combs et al. relates to edema, that is, fluid accumulation in the lungs. By contrast, the present claims all presently recite a fluid shift away from the thorax (claim 29 has been amended to be consistent with the other claims in this regard, and to put claim 29 in better form for appeal), rather than any fluid shift toward the thorax as is associated with edema. Therefore, Combs et al., Pitts Crick et al., and Erlebacher et al. all fail to disclose—and actually expressly teach away from—the present claims, which relate to providing a therapy in response to detection of a fluid shift away from the thorax.

The present Final Office Action responded to the Applicant's previous remarks by stating:

The Applicant's arguments filed 8/14/03 have been fully considered but they are not convincing.

The Applicant asserts that Combs et al. relate to edema ("fluid shift toward the thorax") and not hypotension, ("fluid shift away from the thorax") as claimed by

the Applicant. The Examiner disagrees. Edema is recognized to be fluid collection and hypotension is recognized to be low blood pressure. Low blood pressure is occasionally associated with a fluid shift in the body from the thorax/lungs to the extremities and also associated in varying degrees with a failing heart circulation. The monitoring of edema, collection of fluid in the lungs and a shift of fluid collected in the lungs to the extremities, is significant to the instant invention as it can be an indicator of cardiac circulatory issues and impending/existing low blood pressure issues.

In response to the applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., hypotension) is not recited in the rejected claims 1 – 12 and 13 -35. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(Final Office Action at 5.) Applicant thanks the Examiner for these helpful clarifying remarks amplifying the bases of the rejection. Applicant respectfully responds to the same.

First, for each of the rejected claims 1 – 12 and 13 – 35, Applicant does not rely on any language not present in these claims (e.g., “hypotension”). Instead, Applicant relies only on the language recited or incorporated in these claims. Each of these claims 1-12 and 13 – 35 that does not recite or incorporate “hypotension” presently recites or incorporates “a fluid shift away from the thorax.” Applicant also notes that the recited “detected increase in the baseline portion of the thoracic impedance” signal also corresponds to a fluid shift away from the thorax, because a fluid shift away from the thorax results in an increase in the baseline portion of the thoracic impedance signal. In sum, Applicant relies only on the language recited or incorporated in the claims. Such language expressly or inherently recites or incorporates a fluid shift away from the thorax. Applicant has searched the Combs et al. reference in vain for any disclosure of a fluid shift away from the thorax. Applicant can find none.

Second, Applicant respectfully takes issue with the rejection's assertion that “the monitoring of edema, collection of fluid in the lungs and *a shift of fluid collected in the lungs to the extremities*, is significant to the instant invention as it can be an indicator of cardiac circulator issues and impending/existing low blood pressure issues.” (*See Office Action at 5; emphasis added*) The rejection has acknowledged that edema is manifested by increased water contained in the lungs. (*See id.* at 2.) However, how does such water accumulated and contained within

the lungs somehow leave the lungs and shift away from the thorax? Applicant can find absolutely no disclosure of this in Combs et al. To the extent that the shifting away from the thorax of water accumulated and contained within the lungs is notoriously well known in the art, Applicant respectfully objects such reliance on Official Notice, and respectfully requests that the Examiner provide a reference to support such an assertion. *See* MPEP Section 2144.03.

Applicant respectfully notes that a standard medical dictionary appears to take exactly the opposite position, defining pulmonary edema as

diffuse *extravascular* accumulation of fluid in the pulmonary tissues and air spaces due to changes in hydrostatic forces in the capillaries or to increased capillary permeability; it is marked by intense dyspnea.

(See Dorland's Pocket Medical Dictionary, 25th ed. at 269 (emphasis added). Because pulmonary edema causes fluid to accumulate *outside* the blood vessels in pulmonary tissues and air spaces, Applicant is simply unable to understand exactly how the rejection can take the position that such accumulated *extravascular* interstitial fluid from pulmonary edema will somehow leave the lungs and shift away from the thorax toward the extremities. Again, Applicant respectfully requests a reference for any such assertion.

Because Combs et al., which relates to edema, apparently pertains only to water accumulated and contained within the lungs, Applicant respectfully submits that it does not disclose—and actually teaches away from—using a fluid shift away from the thorax, or providing a therapy to the subject's heart based at least in part on a baseline portion of the detected thoracic impedance associated with a fluid shift away from the thorax. Because all elements recited or incorporated in claims 1 – 12 and 13 – 35 are not disclosed in Combs et al., Applicant respectfully requests withdrawal of this basis of rejection of these claims.

2. Claims 1 – 8, 15 – 20 and 30 were rejected under 35 U.S.C. § 102(e) for anticipation by Pitts Crick et al. (U.S. Patent No. 6,104,949). Applicant respectfully traverses on the same grounds as discussed above with respect to Combs et al., for the reasons previously made of record, and for the further reasons discussed below.

The rejection using Pitts Crick et al. states:

Fluid movement in and out of the lungs is deemed to read on fluid movement in and out of the thorax. Pitts Crick et al. explicitly disclose movement “of fluid in the thoracic cavity, especially in and around the lungs” (col. 4 @ 55-57) and

“impedance changes caused by fluid changes in trans-thoracic tissues, especially in the lungs” (col. 5 @ 34 – 39).

(See Office Action at 6.) Although Pitts Crick et al. acknowledges posture-related fluid shifts affecting transthoracic impedance, it apparently treats such information not as a desirable signal of interest, but rather, as *noise* confounding its edema assessment. More particularly, Pitts Crick et al. states:

These impedance measurements should represent the impedance changes caused by fluid changes in the trans-thoracic tissues, especially in the lungs, due to the patient’s posture changing. Therefore, it is important to either filter or collect several samples and calculate the average, to remove [it] and cardiac or respiratory component from the signal.

(Pitts Crick et al. at column 5, lines 36 - 42.) Because Pitts Crick et al. apparently operates to correlate to—and then remove—the effect of the patient’s postural changes, Applicant respectfully submits that it actually teaches away from these claims.

Moreover, Pitts Crick et al. also teaches away from providing a therapy that assists in shifting fluid back toward the thorax, as presently recited or incorporated in these claims. More particularly, Pitts Crick et al. discusses how its therapy operates by stating:

If such treatments are successful, then the values sensed by the device should move in a direction opposite to that Shown in FIGS. 4A, 4B, and 4C. That is if a patient with severe HF, with an impedance response as shown in FIG. 4C, receive adequate treatment, the resulting curve might convert to FIG. 4B and patient with moderate HF as in FIG. 4B might convert to FIG. 4A.

(Pitts Crick et al. at column 6, lines 43 – 49.) As seen in these figures of the Pitts Crick et al. reference, the therapy used by Pitts Crick et al. actually increases thoracic impedance, which, as explained above, corresponds to shifting fluid away from the thorax. By contrast, Applicants claims presently recite or incorporate providing a therapy to shift fluid back toward the thorax. Therefore, Pitts Crick et al. actually teaches away from the present claims. Therefore, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

3. In the Office Action, claims 1 – 8, 13 – 20 and 30 were rejected under 35 U.S.C. § 102(e) for anticipation by Erlebacher et al. (U.S. Patent No. 6,473,640). Applicant respectfully traverses on the same grounds as discussed above with respect to Combs et al. and for the

reasons previously made of record. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

4. In the Office Action, claims 13 and 14 were rejected under 35 USC § 102(b) for anticipation by Sheldon et al. (U.S. Patent No. 6,044,297). Applicant respectfully traverses on the same grounds discussed above with respect to Combs et al. and for the reasons previously made of record, and for the further reasons discussed below.

The Final Office Action asserts that Sheldon et al. discloses detecting hypotension. (*See* Office Action at 10 (citing Sheldon et al. at column 6, lines 53 – 65 and column 7 at lines 27 - 36). However, Applicant can find no disclosure in Sheldon et al. of detecting hypotension using an implantable medical device to indicate the hypotension, as presently recited or incorporated in these claims. Instead, the cited portion of Sheldon et al. merely states:

In both cases, the actual orientations of the sensitive axes of the DC accelerometers in the IMD, corresponding to the X, Y and Z device axes, with respect to the ideal X, Y and Z axes are determined. Corrected DC accelerometer output signals are derived therefrom and are compared to a set of stored thresholds for each body posture to determine actual body posture.

In accordance with the preferred embodiments of the invention, the stored posture and activity levels may be retained in a monitor and/or be employed to control the delivery of a variety of therapies, including pacing, cardioversion/defibrillation, other body stimulation therapies, and drug delivery therapies. . . .

Medical personal [sic] may better deal with patients with Orthostatic Hypotension from a record of the amount of time in standing, sitting, and supine positions, relative to significant events such as fainting or feeling faint, which an IMD having the invention can easily store. An IMD can provide rapid atrial and/or dual chamber pacing based on knowledge of when the patient is in an or relatively upright posture. Studies have shown increased pacing rates to be of benefit to some patients with severe postural hypotension, so there is ready use for this type of posturally enhanced IMD.

(Sheldon et al. at column 6, lines 53 – 65.) However, Applicant can find nothing in the cited passage referring to detecting hypotension using an implantable medical device using transthoracic impedance, as presently recited or incorporated in these claims. Instead, the Sheldon et al. device apparently increases pacing rate whenever the patient is upright, regardless of whether the patient is hypotensive. By contrast, the present claims are directed toward using

an implantable medical device to detect hypotension, rather than posture, and providing therapy in response to the detected hypotension. Therefore, the present claims avoid inappropriately providing treatment when the patient is upright, but not hypotensive. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection.

The Final Office Action also asserts that Sheldon et al. discloses detecting postural hypotension. (*See* Office Action at 10 (citing Sheldon et al. at column 7, line 28).) The entire sentence that includes the cited passage merely states:

Medical personal [sic] may better deal with patients with Orthostatic Hypotension from a record of the amount of time in standing, sitting, and supine positions, relative to significant events such as fainting or feeling faint, which an IMD having the invention can easily store.

(Sheldon et al. at column 7, lines 27 – 31.) Although this passage indicates that medical personnel can deal with patients with orthostatic hypotension, it fails to disclose detecting orthostatic hypotension using an implantable medical device using transthoracic impedance, as presently recited or incorporated in these claims. For example, even if the IMD of Sheldon et al. stores a patient's fainting as an event, it presumably does so using its posture detector to detect that the patient has fainted. However, postures may or may not be correlated with hypotension, as discussed previously. In sum, nothing in the cited passage of Sheldon et al. discloses using an implantable medical device to detect hypotension using transthoracic impedance.

The Final Office Action also asserts that Sheldon et al. discloses detecting non-postural hypotension. (*See* Office Action at 10 (citing Sheldon et al. at column 7, line 44).) The entire sentence that includes the cited passage states:

Together with monitoring heart rate drop, more effective support pacing (at high rates, for example) therapy for Vasovagal Syncope (VVS) can be supplied by a pacemaker that notices that a patient stood up contemporaneously with a rapid drop in heart rate.

(*See* Sheldon et al. at column 7, lines 42 – 46.) Applicant can find nothing in the cited passage that discloses detecting non-postural hypotension. Instead, the cited passage discloses detecting a drop in heart rate, not hypotension. Moreover, the cited passage discloses detecting a drop in heart rate that occurs contemporaneously with the patient standing up. Therefore, the detected

VVS is apparently postural in nature, rather than non-postural as asserted in the Office Action.

Accordingly, Applicant respectfully requests withdrawal of this basis of rejection.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney 612-373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

AVRAM SCHEINER ET AL.

By their Representatives,

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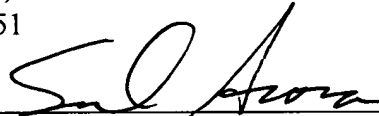
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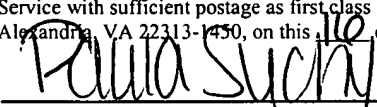
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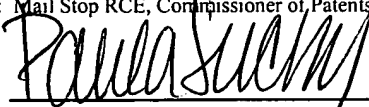

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